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GP:1631

## Docket No. VPI/96-03 DIV 2 RCE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#### PATENT APPLICATION

Applicants

Keith P. Wilson, et al.

Application No.:

09/678,016 Confirmation No.: 7947

Filed

October 2, 2000

For

METHODS OF USING THE STRUCTURE

COORDINATES OF MOLECULES COMPRISING AN

IMPDH-LIKE BINDING POCKET

Group Art Unit :

1631

Examiner

: Marianne P. Allen

New York, New York February 24, 2004

Hon. Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

Express Mail mailing label number EV133110620US.

Date of Deposit February 24, 2004

I hereby certify that this paper/fee is being deposited with the United States Postal Service "EXPRESS MAIL POST OFFICE TO ADDRESSEE" service under 37 C.F.R. 1.10 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Enclosures:

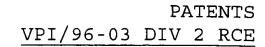
(1) Transmittal Letter (in dupl.);

(2) Information Disclosure Statement;

(3) Form PTO-1449;

(4) Copies of fifteen (15) references; and

(5) Postcard.





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New York, New York February 24, 2004

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

# TRANSMITTAL LETTER FOR INFORMATION DISCLOSURE STATEMENT

Sir:

Transmitted herewith is an Information Disclosure

Statement in the above-identified application. This Statement is submitted before the mailing date of the first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114.

In accordance with 37 C.F.R. § 1.97, submission of this Statement requires no fee. However, if for any reason a fee is due, the Director is hereby authorized to charge payment of any additional fees required in connection with this Information Disclosure Statement to Deposit Account No. 06-1075. A duplicate copy of this letter is transmitted herewith.

Respectfully submitted,

James F. Haley, Jr. (Reg. No. 27,794)

Li Su (Reg. No. 45,141)

Attorneys for Applicants

Lawrence M. Brown (Reg. No. 52,660)

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Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §§ 1.56 AND 1.97

Sir:

Pursuant to 37 C.F.R. §§ 1.56 and 1.97, applicants, through their attorney, make of record the documents listed below. A completed Form PTO-1449 listing all of the documents in alphabetical order is enclosed herewith.

#### United States Patents

Inventor	Serial No.	<u>Issue Date</u>
Carter	4,833,233	May 23, 1989
Subbiah	5,353,236	October 4, 1994
Sjogren	5,380,879	January 10, 1995
Patterson et al.	5,444,072	August 22, 1995
Srinivasan et al.	5,557,535	September 17, 1996

## Foreign Patent Applications

<u>Applicant</u>	Publication No.	<u>Publication Date</u>
Arch Dev Corp.	WO 90/01545	February 22, 1990
Leland Stanford	WO 94/01105	January 20, 1994
Syntex Inc.	WO 94/12184	June 9, 1994
Amgen Inc.	WO 94/17185	April 8, 1994
Immunex Corp.	WO 94/25860	November 10, 1994

#### Articles

The Protein Data Bank (formerly <a href="www.pdb.bnl.gov;">www.pdb.bnl.gov;</a> now <a href="www.rcsb.org">www.rcsb.org</a>).

\*Balbes, L.M. et al., "A Perspective of Modern Methods in Computer-Aided Drug Design," in <u>Reviews in Computational</u> Chemistry, K.B. Lipkowitz and D.B. Boyd, Eds., VCH Publishers, New York, 5, pp. 337-379 (1994).

\*Bartlett, P.A. et al., "CAVEAT: A Program to Facilitate the Structure-Derived Design of Biologically Active Molecules," in Molecular Recognition in Chemical and Biological Problems, S.M. Roberts, Ed., Royal Society of Chemistry, Special Publication No. 78, pp. 182-196 (1989).

Böhm, H.J., "The Computer Program LUDI: A New Method For The De Novo Design of Enzyme Inhibitors", <u>Journal of Computer-Aided</u>
<u>Molecular Design</u>, 6, pp. 61-78 (1992).

Bryan, P.N., "Protein Engineering", <u>Biotech Adv.</u>, 5, pp. 221-234 (1987).

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- \*Claude Cohen, N. et al., "Molecular Modeling Software and Methods for Medicinal Chemistry", <u>Journal of Medicinal</u> Chemistry, 33(3), pp. 883-894 (1990).
- \*Eisen, M.B. et al., "HOOK: A Program for Finding Novel Molecular Architectures that Satisfy the Chemical and Steric Requirements of a Macromolecule Binding Site," <u>Proteins Struct.</u> Funct. Genet., 19, pp. 199-221 (1994).
- \*Gillet, V. et al., "SPROUT: A Program for Structure Generation," <u>J. Comp. Aid. Molec. Design</u>, 7, pp. 127-153 (1993).
- \*Goodford, P.J., "A Computational Procedure for Determining Energetically Favorable Binding Sites on Biologically Important Macromolecules," J. Med. Chem., 28, pp. 849-857 (1985).
- \*Goodsell, D.S. et al., "Automated Docking of Substrates to Proteins by Simulated Annealing," <u>Proteins Struct. Funct.</u> <u>Genet.</u>, 8, pp. 195-202 (1990).
- Gregory, C.R. et al., "Treatment With Rapamycin and Mycophenolic Acid Reduces Arterial Intimal Thickening Produced by Mechanical Injury and Allows Endothelial Replacement," <u>Transplantation</u>, 59(5), pp. 655-661 (March, 1995).
- \*Guida, W.C., "Software for Structure-Based Drug Design," <u>Curr.</u> <u>Opin. Struct. Biology</u>, 4, pp. 777-781 (1994).
- Hansch, C. et al., "Comparison of the Inhibition of Escherichia coli and Lactobacillus Casei Dihydrofolate Reductase by 2,4-diamino-5-(substituted-benzyl) pyrimidines; quantitative Structure-Activity Relationships, X-Ray Crystallography and Computer Graphics in Structure-Activity Analysis," Chemical Abstracts, 97:298f, p. 29 (1982); Journal of Medicinal Chemistry, 25, pp. 777-84 (1982).
- Huete-Pérez, J.A. et al., "Identification of the IMP Binding Site in the IMP Dehydrogenase From *Tritrichomonas Foetus*," Biochemistry, 34, pp. 13889-13894 (October, 1995).
- Jancarik, J. et al., "Sparse Matrix Sampling: A Screening Method for Crystallization of Proteins," <u>J. Appl. Cryst.</u>, 24, pp. 409-411 (1991).
- Kajihara, A. et al., "Protein Modelling Using a Chimera Reference Protein Derived From Exons," <u>Protein Eng.</u>, 6, pp. 615-620 (1993).

- \*Kuntz, I.D. et al., "A Geometric Approach to Macromolecule-Ligand Interactions," <u>J. Mol. Biol.</u>, 161, pp. 269-288 (1982).
- \*Lauri, G. and Bartlett, P.A., "CAVEAT: A Program to Facilitate the Design of Organic Molecules," <u>J. Comp. Aid. Molec. Design</u>, 8, pp. 51-66 (1994).
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- Makara, G.M. et al., "Nuclear Magnetic Resonance and Molecular Modeling Study on Mycophenolic Acid: Implications for Binding to Inosine Monophosphate Dehydrogenase," J. Med. Chem., 39, pp. 1236-1242 (March, 1996).
- Martin, Y.C., "3D Database Searching In Drug Design," <u>Journal of Medicinal Chemistry</u>, 35 (12), pp. 2145-54, (June 12, 1992).
- \*Miranker, A. and Karplus, M., "Functionality Maps of Binding Sites: A Multiple Copy Simultaneous Search Method," <u>Proteins Struct. Funct. Genet.</u>, 11, pp. 29-34 (1991).
- \*Meng, E.C. et al., "Automated Docking with Grid-Based Energy Evaluation," <u>Journal of Computational Chemistry</u>, 13, pp. 505-524 (1992).
- Montero, C. et al., "Demonstration of Induction of Erythrocyte Inosine Monophospate Dehydrogenase Activity in Ribavirin-Treated Patients Using a High Performance Liquid Chromatography Linked Method," Clinica Chimica Acta, 238, pp. 169-178 (August, 1995).
- Moon, J.B. et al., "Computer Design of Bioactive Molecules: A method for Receptor-Based De Novo Ligand Design," <u>Proteins</u>, <u>Structure</u>, <u>Functions and Genetics</u>, 11, pp. 314-328 (1991).
- Morris, R.E., "New Small Molecule Immunosuppressants for Transplantation: Review of Essential Concepts," <u>The Journal of Heart and Lung Transplantation</u>," 12, pp. S275-S286 (1993).
- Musil, D. et al., "The Refined 2.15 Å X-Ray Crystal Structure of Human Liver Cathepsin B: the Structural Basis for its Specificity," EMBO J., 10(9), pp. 2321-2330 (1991).

\*Navia, M.A. and Murcko, M.A., "Use of Structural Information in Drug Design," <u>Current Opinion in Structural Biology</u>, 2, pp. 202-210 (1992).

\*Nishibata, Y. and Itai, A., "Automatic Creation of Drug Candidate Structures Based on Receptor Structure. Starting Point for Artificial Lead Generation," <u>Tetrahedron</u>, 47, pp. 8985-8990 (1991).

Russell, A.J. et al., "Rational Modification of Enzyme Catalysis by Engineering Surface Charge," <u>Nature</u>, 328, pp. 496-500 (1987).

Sielecki, A.R. et al., "Structure of Recombinant Human Renin, a Target for Cardiovascular-Active Drugs, at 2.5 Å Resolution," Science, 243, pp. 1346-1351 (1989).

Sintchak, M.D. et al., "Structure and Mechanism of Inosine Monophosphate Dehydrogenase in Complex with the Immunosuppressant Mycophenolic Acid," <u>Cell</u>, 85, pp. 921-930 (June 14, 1996).

Uhlin, U. et al., "Crystallization and Crystallographic Investigations of Ribonucleotide Reductase Protein R1 From Escherichia Coli," FEBS Lett., 336(1), pp. 148-152 (1993).

\*Whitby, F.G. et al., "Preliminary X-Ray Crystallographic Analysis of *Tritrichomonas foetus* Inosine-5'-Monophosphate Dehydrogenase," <u>Proteins: Structure, Function, and Genetics</u>, 23, pp. 598-603 (1995).

Wright, C.S. et al., "Structure of Subtilisin BPN'at 2.5 Å Resolution," <u>Nature</u>, 221, pp. 235-242 (1969).

Applicants have enclosed herewith copies of the documents indicated with a "\*". Pursuant to 37 C.F.R. § 1.98(d), the remaining documents cited herein are not enclosed because they were submitted with applicants' April 11, 1997 and September 26, 1997 Information Disclosure Statements and cited by the Examiner in a August 21, 1997 Office Action in United States application Serial No. 08/640,164, from which the present

application claims priority under 35 U.S.C. § 120. Each of the cited documents is listed in the enclosed Form PTO-1449.

Applicants will provide copies of these documents upon the request of the Examiner.

Applicants respectfully request that the above-cited documents be (1) fully considered by the Examiner during the course of the examination of this application and (2) printed on any patent issuing from this application. Applicants also request that a copy of the enclosed Form PTO-1449 duly initialed by the Examiner be forwarded to the undersigned with the next communication.

Respectfully submitted,

James F. Haley, Jr. (Reg. No. 27,794)

Li Su (Reg. No. 45,141)

Attorneys for Applicants

Lawrence M. Brown (Reg. No. 52,660)

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U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO. VPI/96-03 DIV 2 RCE

SERIAL NO. 09/678,016

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

APPLICANT
Keith Wilson et al.

FILING DATE

October 2, 2000

(RCE filed February 13, 2004)

GROUP 1631

#### **U.S. PATENT DOCUMENTS**

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	4,833,233	05/23/89	Carter	530	363	
	5,353,236	10/04/94	Subbiah	364	499	
	5,380,879	01/10/95	Sjogren	549	310	
	5,444,072	08/22/95	Patterson et al.	514	320	
	5,557,535	9/17/1996	Srinivasan et al.	364	496	

#### FOREIGN PATENT DOCUMENTS

EXAMINER DOCUMENT NUMB	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	CLIDCI ACC	TRANSLATION	
INITIAL	DOOGWENT NOWBER	DATE	COUNTRI	CLASS	SUBCLASS	YES	NO
	WO 90/01545	22/02/90	PCT	C12N	15/00		
	WO 94/01105	20/01/94	PCT	A61K	31/35		-4,
	WO 94/12184	09/06/94	PCT	A61K	31/535		
	WO 94/17185	04/08/94	PCT	C12N	15/27	-	
	WO 94/25860	10/11/94	PCT	G01N	24/00		
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**EXAMINER** 

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EXAMINER	
INITIAL	The Protein Data Bank (formerly www.pdb.bnl.gov; now www.rcsb.org ).
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	Balbes, L.M. et al., "A Perspective of Modern Methods in Computer-Aided Drug Design," in Reviews in Computational Chemistry, K.B. Lipkowitz and D.B. Boyd, Eds., VCH Publishers, New York, 5, pp. 337-379 (1994).
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· ·	Guida, W.C., "Software for Structure-Based Drug Design," Curr. Opin. Struct. Biology, 4, pp. 777-781 (1994).
	Hansch, C. et al., "Comparison of the Inhibition of Escherichia coli and Lactobacillus Casei Dihydrofolate Reductase by 2,4-diamino-5-(substituted-benzyl) pyrimidines; quantitative Structure-Activity Relationships, X-Ray Crystallography and Computer Graphics in Structure-Activity Analysis," Chemical Abstracts, 97:298f, p. 29 (1982); Journal of Medicinal Chemistry, 25, pp. 777-84 (1982).
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FORMIPIFORM49	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. VPI/96-03 DIV 2 RCE	SERIAL NO. 09/678,016
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) EXAMINER INITIAL Jancarik, J. et al., "Sparse Matrix Sampling: A Screening Method for Crystallization of Proteins," J. Appl. Cryst., 24, pp. 409-411 (1991). Kajihara, A. et al., "Protein Modelling Using a Chimera Reference Protein Derived From Exons," Protein Eng., 6, pp. 615-620 (1993). Kuntz, I.D. et al., "A Geometric Approach to Macromolecule-Ligand Interactions," J. Mol. Biol., 161, pp. 269-288 (1982). Lauri, G. and Bartlett, P.A., "CAVEAT: A Program to Facilitate the Design of Organic Molecules," J. Comp. Aid. Molec. Design, 8, pp. 51-66 (1994). Li, R., et al., "A comparison by QSAR Crystallography and Computer Graphics of the Inhibition of Various Dihydrofolate Reductases b 5-(x-benzyl)-2,4-diaminopyrimidines," Chemical Abstracts, 98:17257a, p, 28 (1983); Quantitative Structure Activity Relationships Pharmacol. Chem. Bil., 1, pp. 1-7 (1982).Makara, G.M. et al., "Nuclear Magnetic Resonance and Molecular Modeling Study on Mycophenolic Acid: Implications for Binding to Inosine Monophosphate Dehydrogenase," J. Med. Chem., 39, pp. 1236-1242 (March, 1996). Martin, Y.C., "3D Database Searching In Drug Design," Journal of Medicinal Chemistry, 35 (12), pp. 2145-54, (June 12, 1992). Miranker, A. and Karplus, M., "Functionality Maps of Binding Sites: A Multiple Copy Simultaneous Search Method," Proteins Struct. Funct. Genet., 11, pp. 29-34 (1991). Meng, E.C. et al., "Automated Docking with Grid-Based Energy Evaluation," Journal of Computational Chemistry, 13, pp. 505-524 (1992). Montero, C. et al., "Demonstration of Induction of Erythrocyte Inosine Monophospate Dehydrogenase Activity in Ribavirin-Treated Patients Using a High Performance Liquid Chromatography Linked Method," Clinica Chimica Acta, 238, pp. 169-178 (August, 1995). Moon, J.B. et al., "Computer Design of Bioactive Molecules: A method for Receptor-Based De Novo Ligand Design," Proteins, Structure, Functions and Genetics, 11, pp. 314-328 (1991). Morris, R.E., "New Small Molecule Immunosuppressants for Transplantation: Review of Essential Concepts," The Journal of Heart and Lung Transplantation," 12, pp. S275-S286 (1993). Musil, D. et al., "The Refined 2.15 Å X-Ray Crystal Structure of Human Liver Cathepsin B: the Structural Basis for its Specificity," EMBO J., 10(9), pp. 2321-2330 (1991). Navia, M.A. and Murcko, M.A., "Use of Structural Information in Drug Design," Current Opinion in Structural Biology, 2, pp. 202-210 (1992). Nishibata, Y. and Itai, A., "Automatic Creation of Drug Candidate Structures Based on Receptor Structure. Starting Point for Artificial Lead Generation," Tetrahedron, 47, pp. 8985-8990 (1991).

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

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	Russell, A.J. et al., "Rational Modification of Enzyme Catalysis by Engineering Surface Charge," Nature, 328, pp. 496-500 (1987).
	Sielecki, A.R. et al., "Structure of Recombinant Human Renin, a Target for Cardiovascular-Active Drugs, at 2.5 Å Resolution," Science, 243, pp. 1346-1351 (1989).
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